International Journal of Hyperthermia

ISSN: 0265-6736 (Print) 1464-5157 (Online) Journal homepage: http://www.tandfonline.com/loi/ihyt20

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To cite this article: M. Kikuchi, Y. Amemiya, S. Egawa, Y. Onoyama, H. Kato, H. Kanai, Y. Saito, I. Tsukiyama, M. Hiraoka, S. Mizushina & T. Yamashita (1993) Guide to the use of hyperthermic equipment. 1. Capacitively-coupled heating, International Journal of Hyperthermia, 9:2, 187-203, DOI: 10.3109/02656739309022534

To link to this article: http://dx.doi.org/10.3109/02656739309022534

Published online: 09 Jul 2009.

INT. J. HYPERTHERMIA, 1993, VOL. 9, NO. 2, 187–203

Guide to the use of hyperthermic equipment. 1. Capacitively-coupled heating

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(*Received*

1. Introduction

With the increasing use of hyperthermia in medical centres there is a requirement for a guidebook to heating equipment and thermometry. The Japanese Society of Hyperthermic Oncology (JSHO) committee set up a working group within the QA committee to produce such a guide.

This guide is intended only for the purposes stated below. It is not intended to be a formal regulation or standard to which all heating equipment must conform.

1. Heating systems: to enable performance checks to be carried out and to produce a safety operation guide for the RF capacitively-coupled heating systems which are commonly used in Japan.
2. Phantom: to decide on the type and constitution of a phantom for use in the performance check of the heating system.
3. Thermometry: to define the procedure for checking accuracy and to produce a guide for clinical thermometry using thermal sensors such as thermocouples and thermistors which are used in capacitively-coupled heating.

The following topics are discussed: general description of capacitively-coupled heating system; heating method for capacitively-coupled heating system; set-up for standard test of performance; standard muscle-equivalent agar phantom for 8–13·56 MHz; guidelines for optimal clinical use of capacitively-coupled heating system; thermometric techniques; guidelines for thermometry during treatment; Appendices.

2. Heating equipment

Heating systems using electromagnetic energy are commonly used in clinical hyperthermia. These can be divided into three types:

1. Equipment which can heat tissues up to about 2 cm depth from the surface to approximately 43°C: these are 2450 MHz microwave radiating systems.
2. Equipment which can heat to about 43°C up to 3–4 cm depth from the surface: these are 434 and 915 MHz microwave radiating systems.

This article is a translated version of the Japanese QA Guide produced by the Japanese Society of Hyperthermic Oncology.

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3. Equipment which can heat to about 43°C to a depth of more than 5 cm from the surface: these are RF (8 and 13·56 MHz) capacitively-coupled heating systems and annular phased array system (APAS) (55–100 MHz).

When using equipment which can produce heating at depth (3) above, greater care is needed for safety than in the case of superficial heating systems. Since it is difficult to heat deep-seated tumours selectively, a larger region including the surrounding normal tissues must be heated.

3. RF capacitively-coupled heating technique

3.1. *Characteristics of RF capacitively-coupled heating*

RF is an abbreviation for radiofrequency. In engineering terms it refers in general to the frequency band from 10 kHz to 100 GHz. In hyperthermia RF refers to a narrower frequency band from several MHz to several tens of MHz, and is used to distinguish from the higher-frequency microwave region. When the restricted definition relevant to hyperthermia is used, RF is a very useful term since the characteristics of e-m waves in this restricted band remain similar.

In the capacitively-coupled heating method as shown in Figure 1 currents flow between the electrodes through living tissue and generate heat through dielectric losses in the tissue. In the early stages of research with RF heating it was thought that RF currents flowed in a cylinder in which the top and bottom were formed by the electrodes. Thus, an electrode whose size is similar to the diameter of tumour was used. Lately it was recognized that such a small electrode could not heat a deep-seated tumour effectively. The reason for this discrepancy was the assumption that the currents flowed within a cylinder. Actually, RF current flow diverges with increasing depth, leading to a reduction in current density (current flow across unit area) with increasing depth.

It is now well accepted that it is feasible to achieve deep heating when using large electrodes. When their diameter is in the range of 1·0–1·5 times or more of their separation, most of the current flows within the cylindrical volume formed by the electrodes and this volume is heated fairly uniformly if the tissue in it is homogeneous. Although deep heating is achieved using large electrodes, much power is wasted in a large volume of normal tissues. Moreover, it is difficult to make a good contact between the electrode and the body. Therefore, appropriate size of the electrodes for clinical use is chosen with these points in mind.

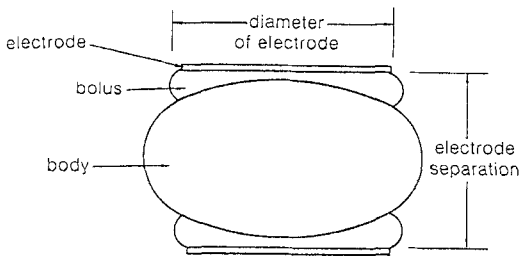

Figure 1. Relationship between the diameter and separation of electrodes in RF capacitively-coupled heating technique.

When using a pair of electrodes of differing sizes the current density below the smaller electrode is greater than that below the larger one, so there is a difference in power deposition beneath the electrodes. Thus electrodes of differing size are effective when heating superficial tumours.

As mentioned above, it is not possible to deposit energy selectively in a deep-seated tumour and not in normal tissue. However, even though the power deposition is similar, there is a difference in blood flow cooling between tumour and normal tissues, so the temperature increase produced in tumour may be greater than that in normal tissues.

Thus the RF capacitively-coupled technique can be considered to be a method for local and/or regional heating.

3.2. *Precautions in use*

Below we describe briefly some precautions which should be taken when using this heating technique. To heat effectively it is necessary to achieve impedance matching between the generator and body. It is difficult to predict the value of impedance required for matching because the impedance of the body is dependent upon the region treated, condition of the body, diameter of electrodes, electrode spacing and degree of contact. A circuit for impedance matching is therefore provided as part of the system to enable an optimum match to be achieved by adjustment.

Since there is a tendency to overheat the region of contact between applicator and body and the subcutaneous fat layer, chilled water must be circulated within the applicator to prevent burns to these regions. Also, the region beneath the electrode may be overheated as a result of edge effects, i.e. a concentration of current at the edges of the electrodes. This effect limits the input power so a countermeasure must be taken.

Furthermore, the electrodes should remain parallel (Figure 1). If the electrodes converge, there is an increase in current density in this region and a risk of overheating. When using larger electrodes it is difficult to achieve parallelism so it is necessary to fill the space between electrodes and the body with bolus. The bolus reduces the edge effect and increases the effective size of the electrodes. However, in this case care must be taken since the electrode spacing is increased by the presence of the bolus. Since more power is absorbed in the bolus, a more powerful generator is required.

By taking the precautions described above it should be possible to heat both superficial and deep tissues.

4. Guidelines for checking the performance of RF capacitively-coupled heating systems

4.1. *Introduction*

The performance of the heating system is checked by measuring power. The most important factor to consider is how much power can be put into the body. Power is usually measured at the output of the final power amplifier with the load impedance matched to 50 Ω. However, the power measured in this way is not that absorbed in the body since some power is absorbed in the matching network, balun (unbalanced transformer), the cooling water in the electrode and the bolus. The amount of power transmitted to the body in relation to the total measured power must be determined. This relationship varies between individual systems and types of bolus. When comparing clinical data the actual power absorbed by the body should be used.

It is recommended that personnel who are inexperienced in the clinical use of the heating system should practise the procedures outlined below:

The operator should be familiar with the relationship between input power and the

setting of the power control so that accidental application of excess power to the patient is prevented. In particular, care will be needed in this respect with future heating systems which are expected to have higher power.

It is advisable to perform the check described below at 6-monthly intervals even if the system is working well in clinical use. This check should also be performed when the applicator or bolus is changed, or if a malfunction of the heating system is noted in clinical use (in which case the treatment must be terminated).

The results of the check should be compared with those obtained on the previous occasion. The heating system should be inspected and corrective action taken if there is a significant difference between the results of the two checks.

4.2. *Test*

1. Confirm that the wiring and connections are correct.
2. Place the applicator on the phantom for power measurement, insert the temperature sensors and measure the temperature (see §4.3.1).
3. Set the power indicator to one-third of the maximum power and adjust the matching circuit so as to achieve a standing wave ratio, SWR (see comment A in Appendix B) of less than 1·5. If it is not possible to achieve an SWR of less than 1·5, check the connection between applicator and generator, the contact between applicator and bolus and the arrangement of applicator, cooling water and phantom (see comment B in Appendix B).
4. Adjust the matching three or four times whilst increasing the power.
5. Adjust the matching at maximum power.
6. Turn off the output switch and wait until the phantom cools to within 1 °C of its original temperature.
7. Start the power measurement:
   (a) Turn on the output switch and increase the output to maximum within 10 s of turning on.
   (b) start the timer and at the same time measure the temperatures. Maintain optimum matching by adjusting the matching control so as to minimize SWR.
   (c) Measure the temperature every 30 s.
   (d) Stop the measurement when the temperature has increased by 5 °C.
   (e) Calculate the heating power using the equation shown in §4.3.3.
8. Record room temperature, the positions of controls, the SWR, output power and the readings of all meters.

4.3. *Calculation of heating power*

The following describes the heating power measurement referred to in §4.2.7. The standard muscle-equivalent agar phantom described in the next section is used in the measurement. The heating power is defined as

Heating power = power delivered to the body by the heating system
= forward power − reflected power − power absorbed in bolus, etc (see §4.1.).

4.3.1. *Comments on cylindrical phantom for heating power measurement*

Dimensions: 25 cm diameter, 16 cm high.
Weight: 7·85 kg.
Ingredients: agar plus additives (see §5.).

Electrodes: are placed on the top and bottom surfaces of the phantom.

Position of temperature measurements: three points in the plane at mid-height of phantom; one on central axis and the others diametrically opposed and 5 cm off-axis. Sensors are inserted radially. The mean value of the increases in temperature at these three locations is taken to represent the increase in temperature of the phantom. A schematic diagram of the set up is shown in Figure 2.

Room temperature: 22–25°C.

4.3.2. *Electrodes*

Dimensions: 25 cm diameter.

Before measurements, the cooling water is circulated through the electrodes for a short time and then stopped. Boli must be set up as part of the test if the clinical arrangement includes use of boli. In this case, water must be circulated through the boli for a short time and then stopped before measurements are made.

4.3.3. *Calculation of heating power.* Heating power is assumed to be absorbed uniformly throughout the phantom.

$$\text{Amount of heat } Q = 0{\cdot}24 \times W \times t(\text{cal})$$

where W=heating power (W)

t=heating time (s)

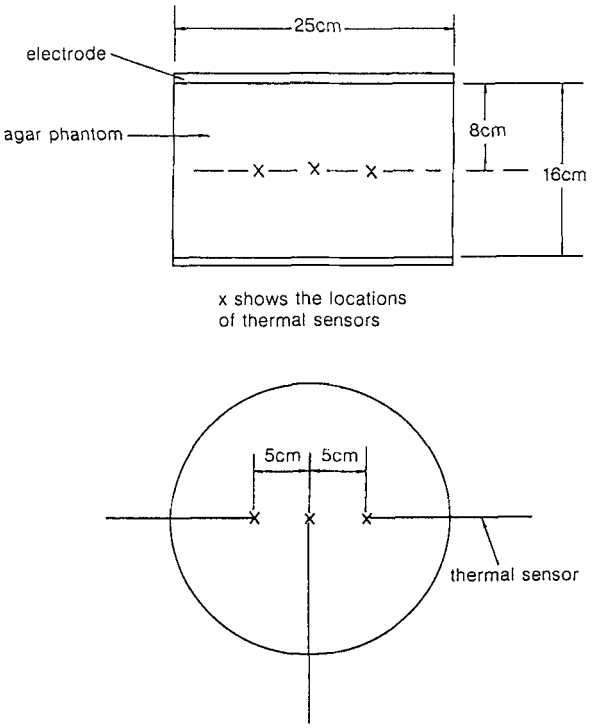

Figure 2. Agar phantom used in the heating power measurement; the positions of the electrodes and thermosensors are shown.

Temperature increase $K=Q/(c\times m)$ (°C)

where c=specific heat (cal $°C^{-1}$ g^{-1})
m=mass of the phantom (g)

$$W=K\times c\times m/(0\cdot24\times t)$$

Figure 3 shows a rapid means of determining the heating power from the increase in temperature. The abscissa refers to the temperature increase and the ordinate the heating power. The parameters on the lines refer to heating time.

The results of the above measurement and calculation do not always predict the correct temperature rise produced in the body.

5. Standard-muscle equivalent agar phantom for use at frequencies 8–13·56 MHz

5.1. *Composition* (% by weight)

Agar powder	4%
NaCl	0·24%
NaN_3	0·1%
H_2	95·66%

5.2. *Room temperature:* 22–25°C

5.3. *Dielectric properties*
Permittivity=81
Conductivity=0·62 Sm^{-1}
At temperature=23·5°C and frequency=5–40 MHz
(see comment C in Appendix B)

5.4. *Thermal properties*
Density=1×10^3 kg m^{-3}
Specific heat $c=4\cdot2\times10^3$ J kg^{-1} $°C^{-1}$=1 kcal kg^{-1} $°C^{-1}$

5.5. *Preparation*

When preparing the phantom take care to avoid burning the agar when heating directly by flame and keeping the materials at high temperature for a long time, since this reduces the mechanical strength of the agar phantom.

5.5.1. *Making up to 3 litres of phantom*

1. Place distilled water and agar powder in a beaker and place in an autoclave.
2. Heat at 1 atm for 15 min.
3. After heating add NaCl and NaN_3, stirring well.
4. Pour the solution into a mould which has high thermal conductivity (e.g. metallic).
5. After solidification (which takes about half a day) remove the phantom from the mould. Remove the surface region of the phantom which was in contact with the air and form the phantom into the desired shape. Use sufficient materials to give an excess of about 20% over the desired volume since the surface region in contact with the air contains bubbles and loses water.
6. Wrap the phantom with plastic film to prevent evaporation.
7. Leave the phantom at room temperature for 1 day to allow the temperature distribution to become uniform.

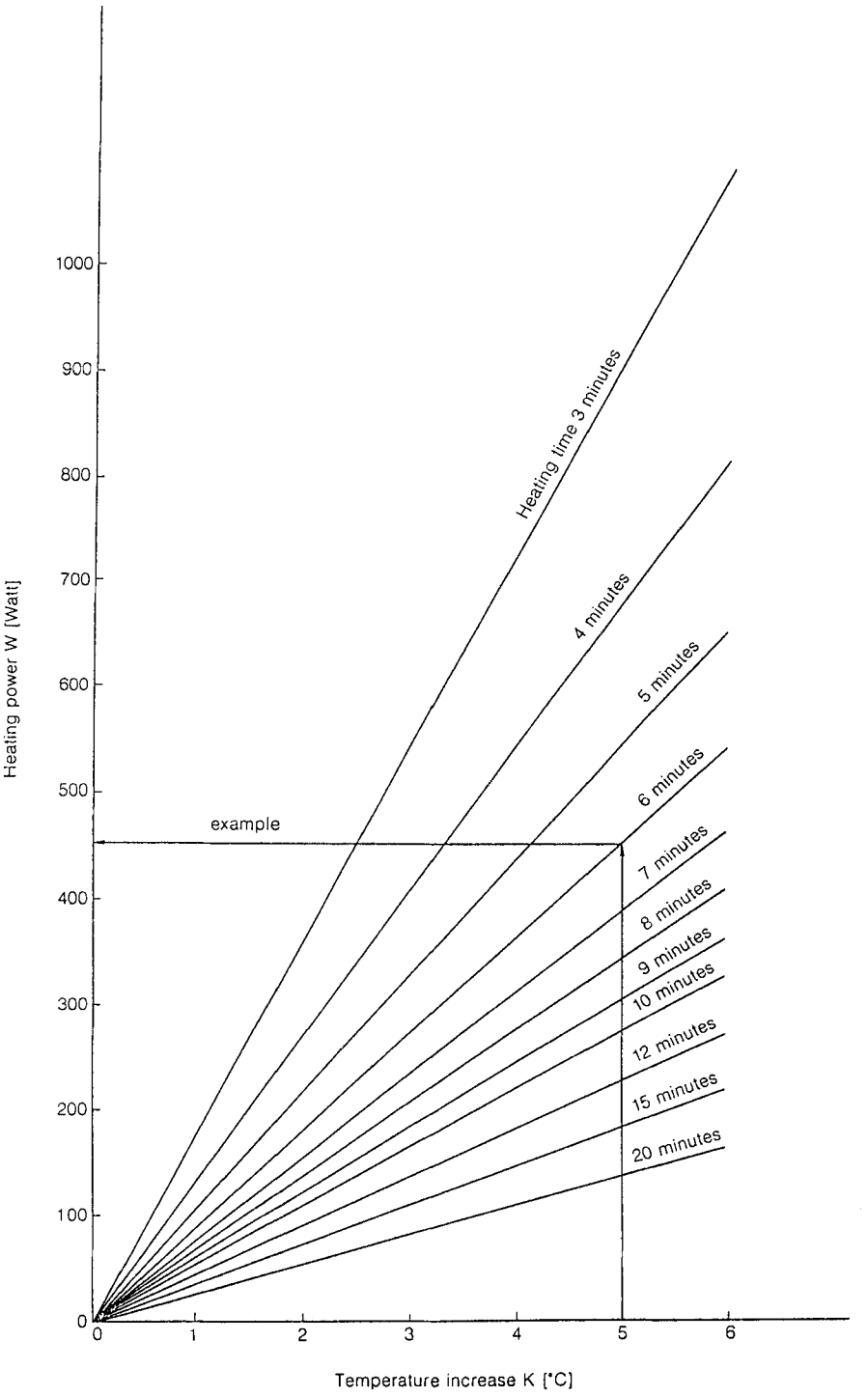

Figure 3. Graphical method for estimating heating power for a phantom 25 cm diameter, 16 cm high.

5.5.2. *Quantities up to 10 litres*

1. Place distilled water and agar powder in a suitable container.
2. Stir whilst heating until boiling occurs.
3. Add NaCl and NaN_3 whilst heating.
4. Pour the solution into a mould which has high thermal conductivity (e.g. metallic).
5. After solidification (which takes about ½ day) remove the phantom from the mould. Remove the surface region of the phantom which was in contact with the air and form the phantom into the desired shape. Use sufficient materials to give an excess of about 20% over the desired volume since the surface region in contact with the air contains bubbles and loses water.
6. Wrap the phantom with plastic film to prevent evaporation.
7. Leave the phantom at room temperature for 1 day to allow the temperature distribution to become uniform.

5.5.3. *Quantities up to 20 litres*

1. Place distilled water in a covered container and heat to 95°C. There should be a hole in the lid to accommodate the shaft of a stirrer.
2. Pour the agar powder into the container, little by little, whilst stirring as quickly as possible but avoiding creation of bubbles.
3. Add NcCl and NaN_3 and place lid on container. Stir the mixture for about 40 min until the agar powder is completely dissolved.
4. After stirring, leave for 5 min to allow bubbles to disperse.
5. Pour the solution into a mould which has high thermal conductivity (e.g. a metal mould).
6. After solidification remove the phantom from the mould. Remove the surface region of the phantom which was in contact with the air and form the phantom into the desired shape. Use sufficient materials to give an excess of about 20% over the desired volume since the surface region in contact with the air contains bubbles and loses water. Wrap the phantom with plastic film to prevent evaporation.
7. Leave the phantom at room temperature for 1 day to allow the temperature distribution to become uniform.

6. Safety guidelines for operation of RF capacitively-coupled heating systems

6.1. *Application*

RF capacitively-coupled heating systems are usually applied to tumours in the limbs, abdomen and pelvic region, although application to tumours in the head and neck region and brain is also possible. To achieve the desired temperature distribution and prevent hot spots, some skill is needed to heat tumours located in the lung, head and neck and brain due to the presence of air or bone in the heated region. It is recommended that the patient's heart rate and body temperature are monitored during heating. This is particularly important when the heart is included in the heated region; in this case previous cardiographic monitoring should be carried out. Care is needed when heating the face or neck region because dizziness or vomiting may be induced by the high temperature of the labyrinth.

6.2. *Hyperthermia-treatment room*

6.2.1. *E-m interference.* Care is needed when the output power is relatively high because the e-m fields may interfere with electronic instruments in the vicinity of the heating system. The use of a shielded room is recommended.

6.2.2. *Treatment couch.* The use of metallic treatment couches is prohibited.

6.3. *Thermometry*

Temperature measurements during heating must be made using a thermometry system capable of operating in the presence of e-m interference. Thermometric techniques are described in §§7 and 8.

6.4. *Knowledge required for safe operation*

Features of RF capacitively-coupled heating technique (see §3.).

1. In general, electrodes should remain parallel.
2. There is a tendency for tissues near to the edges of the electrodes to overheat.
3. When the thickness of the subcutaneous fat layer is greater than 1·5 cm it is generally more difficult, and in some cases may not be possible, to heat deep regions. When there is a fat layer inside the body, care must be taken to avoid overheating it.
4. When air and/or bone are included in the treatment field, RF currents tend to flow around these regions giving rise to the possibility of increased current density and consequently overheating of the tissue in the regions surrounding them.

6.5. *Initial pretreatment check*

Using a phantom such as a wet towel, check the matching to ascertain whether the electrodes are connected to the generator.

6.6. *Heating procedure*

1. Place the electrodes as parallel as possible.
2. Use the bolus to reduce edge effects (the phenomenon of excessive heating near the edge of the electrodes).
3. The use of a gel such as that used for diagnostic ultrasound procedures is sometimes effective in achieving good contact between the electrode and skin, and in reducing edge effects. At first set power at 100 W and adjust the matching between the heating system and the patient. When the reading of the matching meter is different from previous values, care should be taken.
4. Increase the heating power gradually such that the desired power level is achieved after about 5–10 min.
5. Adjust the matching at the desired power level.
6. Heat the patient according to the clinical protocol arranged by medical centres.

6.7. *Problem management*

1. If the patient complains of excessive local heating:
   (a) reduce the heating power,
   (b) check the skin cooling,
   (c) check the position of the electrode,
   (d) check whether there are any extraneous materials,
   (e) improve the contact between the electrodes and the skin,
   (f) talk with the patient, checking that all is well; increase the power gradually and continue to heat the patient.
2. If the patient perspires: If the patient perspires in the region close to the electrodes, keep the area dry to avoid the possibility of RF current flow through the sweat, thus reducing the risk of burning and/or electric shock. It is recommended that the operator wears insulating gloves.
3. If the patient is on a drip during heating: RF current may flow through the liquid of the drip. Keep the drip system and the patient electrically isolated from ground potential.

4. Precaution against operator and/or patient receiving electric shock. Do not insert hypodermic needles during heating.
5. If the patient has a metallic implant (e.g. pacemaker, metal plates used for fracture therapy) care must be taken since RF currents will tend to converge around the implant.
6. In an emergency, turn off the master switch.

6.8. *Positioning of patient during heating*

The supine position is usually adopted although laying on the side will often be acceptable.

6.9. *Treatment after heating*

If inflammation or blistering occurs near the electrodes, treatment for burns and/or skin cooling should be administered.

7. Thermometry

It has been shown that the lethal effect of heat on cells increases by a factor of 2 with each 1 °C increase at temperatures over 42·5 °C. Precise temperature measurements must be made during clinical applications of hyperthermia since high temperatures are required to eradicate the cancer cells whilst the patient's temperature must be maintained within safe levels. Non-invasive thermometry is desirable but at present invasive thermometry is used since non-invasive techniques for routine use in the clinic have not been developed. Thermocouples, high-impedance thermistors with high-impedance leads and optical fibres with thermal sensors are available for invasive thermosensitive probes. The thermocouple thermometer is widely used in Japan and a thermometer designed especially for hyperthermia is available. It is recommended that this thermometer be used for hyperthermia. Care must be taken to ensure that the accuracy of thermocouple thermometers designed for other purposes satisfies the requirements for hyperthermia if such thermometers are used for clinical hyperthermia.

Probes with metallic leads such as thermocouples and thermistors may exhibit artifacts due to e-m interference. Table 1 summarizes the problems arising from EMI. These

Table 1. Problems arising from the use of metallic probes in e-m fields

1. Concentration and reflection of e-m fields by the probe
2. Excessive heating of medium around the probe
3. Excessive heating of the probe itself
4. Noise induced in the probe
5. Noise induced in the thermometry system
6. Error due to thermal conduction along probe

problems can be divided into two main categories; these are local heat generation (induction of hot spot) and artifactual readings caused by the current (noise). The following countermeasures are effective in reducing these problems: use of fine wires for leads, use of insulated sheathing around the wire, twisting the lead wires and inserting a choke coil between the probe and the thermometry system. Most thermometry systems for hyperthermia adopt the use of these countermeasures. In some cases placing lead wires perpendicular to the electric field and the probe away from the applicator may be effective.

The following characteristics for invasive thermometry systems must be determined:

1. principle of operation;
2. the outer diameter, length and type of the probe;

3. accuracy;
4. temperature resolution;
5. stability;
6. response time;
7. sensitivity of e-m interference;
8. effect of presence of catheter;
9. spatial resolution;
10. effect of kinking, bending, etc.;
11. effect of changes in environmental temperature;
12. thermal hysteresis effects;
13. others (such as those associated with particular types of sensors).

In the case of regional heating systems we should be satisfied if the tumour can be heated to a uniformity of 1 °C throughout its volume (including any distortion of the temperature distribution caused by the presence of the thermometer probe). Bearing in mind the performance of currently available thermometers and the errors present in calibration processes, an accuracy of ±0·6°C throughout the treatment is sought in thermometry systems.

Moreover, thermometry systems used in whole-body heating should be more precise than those used in regional heating.

The operator should check periodically that the performance of thermometry systems complies with requirements for clinical treatments. The detailed guidelines are given in the appendix A.

8. Guidelines for thermometry in clinical treatments

The therapeutic effect of hyperthermia is dependent upon temperature and the duration at that temperature. It is also reported that an inhomogeneous temperature distribution is produced when the tumour is heated, and that the lowest temperature achieved correlates with the therapeutic effect. Bearing this in mind, it is recommended that the temperature distribution in the tumour and surrounding normal tissue is measured during every treatment. The guidelines for thermometry in the case of superficial tumours located up to 5 cm from the skin are listed below. Where possible, thermometry in deep-seated tumours should satisfy the same guidelines.

1. The temperatures at the deepest and the central portions of the tumour and at the skin surface should be measured every treatment using at least two probes.
2. Figure 4 shows the temperature measurement points in the tumour and surrounding normal tissue.
3. The position of the tip of the probe should be confirmed using X-CT.
4. Measure the temperatures of the deep aspect of the tumour and the skin surface continuously and record these at least once every 2 min.

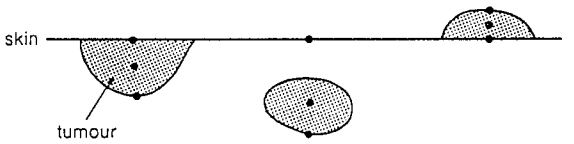

Figure 4. Temperature measurement point.

5. When the temperature–time relationship has reached a plateau, and before the termination of heating, the temperature distribution is measured by means of thermal mapping or the use of a multisensor probe.
6. Record and store the following data:
   (a) the name of the heating system, frequency used, method of heating and heating power (mean, maximum);
   (b) the type, dimensions, shape and position of the applicator;
   (c) whether or not skin cooling was used and, if so, the method adopted and temperature used;
   (d) whether or not a bolus was used and, if so, the type of bolus;
   (e) the name of the thermometry system;
   (f) the location, size and depth of the tumour;
   (g) the direction of implantation and location of the thermometry probe and X-CT confirmation of the probe's location;
   (h) temperature versus time at the deepest aspect of the tumour and skin surface and other measurement points if relevant;
   (i) temperature distribution in the tumour and surrounding normal tissue.

Appendix A: Checking the accuracy of the thermometry system

A.1. *Performance*

A.1.1. *Calibration accuracy.* The accuracy of the thermometry system is to be ±0·3°C when the system is calibrated against a double-tube mercury-in-glass standard thermometer or a double-tube mercury-in-glass working standard thermometer recommended by the QA committee (see comment D in Appendix B).

A.1.2. *Stability with time.* The variation of the temperature reading with time must be less than ±0·1°C during treatment assuming the conditions set for environmental conditions, AC voltage, etc., are met.

A.1.3. *Stability against e-m fields and AC line noise.* Any effects of e-m fields or AC noise on the thermometry system must be less than ±0·2°C.

A.2. *Procedure*

The following procedure should be followed to check that the thermometry system complies with the requirements described above. These checks should be made under the following conditions: room temperature 15–35°C, relative humidity 25–85%.

A.2.1. *Accuracy in comparative calibration.* In this case the accuracy is determined in terms of the difference between the reading of the thermometer and the true temperature.

1. Insert the sensor of the working standard thermometer or other thermometer (which must have an accuracy equal to or greater than the recommended thermometer) and that of the thermometer to be calibrated (the examined instrument) in the centre of the water bath (see comment E in Appendix B). The sensors of the thermometers should be positioned close to each other. The working standard thermometer is immersed perpendicularly in the water bath up to the immersion line which is marked on it. The arrangement is shown in Figure 5.
2. The calibration should be carried out at intervals of 2·5–5°C over the temperature range from 35 to 50°C.

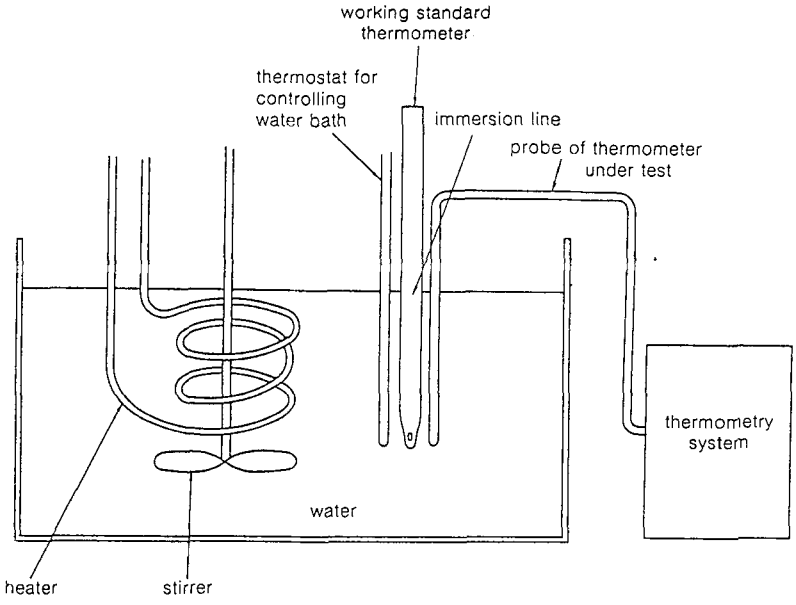

Figure 5. Arrangement for comparative calibration using a water bath.

3. The readings indicated by the thermometer under test and the working standard thermometer are read when the temperature in the water bath is stable (variation less than 0·05°C in 1 min). A series of 10 readings should be made (i.e. *Ts*1, *Tx*1, *Ts*2, *Tx*2, . . . *Tx*10 where *Ts* refers to the readings of the working standard thermometer, *Tx* to the readings of the thermometer under test). The checking procedure is shown in Table 2.
4. Confirm that the accuracy, determined by the procedures of Table 2, is better than ±0·3°C. σ_s and σ_x should be calculated using:

$$\sigma_s = \sqrt{\frac{\sum_{i=1}^{10} (\mathrm{T}si - \bar{\mathrm{T}}s)^2}{9}} \qquad \bar{\mathrm{T}}s = \frac{\sum_{i=1}^{10} \bar{\mathrm{T}}si}{10}$$

$$\sigma_x = \sqrt{\frac{\sum_{i=1}^{10} (\mathrm{T}xi - \bar{\mathrm{T}}x)^2}{9}} \qquad \bar{\mathrm{T}}x = \frac{\sum_{i=1}^{10} \bar{\mathrm{T}}xi}{10}$$

A.2.2. *Temporal stability*

1. Adjust the temperature of the water in the tank to 42·5±0·5°C. Variations should be less than 0·05°C in 1 min.
2. Measure the time dependence of the temperature error of the thermometer according to the method described above in §A.2.1. These measurements should be made at 15 min intervals over a period of 90 min. The procedure is outlined in Table 3.
3. Confirm that the variation in the temperature errors, measured with respect to the initial temperature error, is less than ±0·1°C.

A.2.3. *Stability against electromagnetic fields and AC line noise*

1. Use the phantom described in §4.3.

2. Insert the thermometer probe in one of the following ways:
   (a) insert the sensitive part of the probe along the central axis of the phantom to a depth of 8 cm, or
   (b) insert the probe radially and perpendicularly to the central axis to a depth of 8 cm so that the sensitive part of the probe is on the central axis of the phantom.

   In both cases, a catheter may be used to facilitate probe insertion. The arrangement is shown in Figure 6.

Table 2. Comparative calibration.

Date of calibration:
Calibration carried out by:
Room temperature: °C; humidity: %
Type and reference number of thermometry system under test:
Type and reference number of working standard thermometer:
Accuracy of working standard thermomeer: 2* σt= °C
Type and reference number of water bath used:

	Temperature read	Calibration temperature (°C) 30	35	37·5	40	42·5	45	50
Working standard thermometer	Ts_1							
	Ts_2							
	Ts_3							
	Ts_4							
	Ts_5							
	Ts_6							
	Ts_7							
	Ts_8							
	Ts_9							
	Ts_{10}							
	Mean value $\bar{T}s$							
	Correction Δes							
	Correction for the exposed portion of the working standard thermometer Δee							
	True temperature of working standard thermometer $Tt=\bar{T}s-\Delta es+\Delta ee$							
	Twice standard deviation $2\sigma s$							
Thermometer under test	Tx_1							
	Tx_2							
	Tx_3							
	Tx_4							
	Tx_5							
	Tx_6							
	Tx_7							
	Tx_8							
	Tx_9							
	Tx_{10}							
	Mean value $\bar{T}x$							
	Twice standard deviation $2\sigma x$							
Error of thermometer under test and estimation of comparative calibration	Error of thermometer under Test $E=\bar{T}x-Tt$ comparative accuracy (precision) $\epsilon=\sqrt{(2\sigma s)^2+(2\sigma x)^2+(2\sigma t)^2}$ accuracy $A=E\pm\epsilon$							

Table 3. Stability.

Date of calibration:
Calibration carried out by:
Room temperature: °C; humidity: %
Type and reference number of thermometry system under test:
Type and reference number of working standard thermometer:
Accuracy of working standard thermomeer: $2^* \sigma t =$ °C
Type and reference number of water bath used:

	Temperature read	Elapsed time (min) Initial time	15	30	45	60	75	90
Working standard thermometer	Ts_1							
	Ts_2							
	Ts_3							
	Ts_4							
	Ts_5							
	Ts_6							
	Ts_7							
	Ts_8							
	Ts_9							
	Ts_{10}							
	Mean value $\bar{T}s$							
	Correction Δes							
	Correction for the exposed portion of the working standard thermometer Δee							
	True temperature of working standard thermometer $Tt = \bar{T}s - \Delta es + \Delta ee$							
Thermometer under test	Tx_1							
	Tx_2							
	Tx_3							
	Tx_4							
	Tx_5							
	Tx_6							
	Tx_7							
	Tx_8							
	Tx_9							
	Tx_{10}							
	Mean value $\bar{T}x$							
	Twice standard deviation $2\sigma x$							
Thermometer under test	Error of thermometer under test $E = \bar{T}x - Tt$							

3. Measure the temperature indicated by the thermometer under test at 10 s intervals throughout the following procedure:
   (a) leave the phantom for 2 min with zero output power;
   (b) heat the phantom at 400 W (or at the power level needed to maintain effective temperatures during hyperthermia treatment) for 5 min or until a temperature increase of 3°C has been achieved;
   (c) leave the phantom for 5 min with zero heating power.
   (d) Figure 7 shows an example of the thermometer reading. ΔTn indicates the amount of noise induced by RF. ΔTh indicates local heating induced by RF. Confirm that the sum of ΔTn and ΔTh is less than 0·2°C.

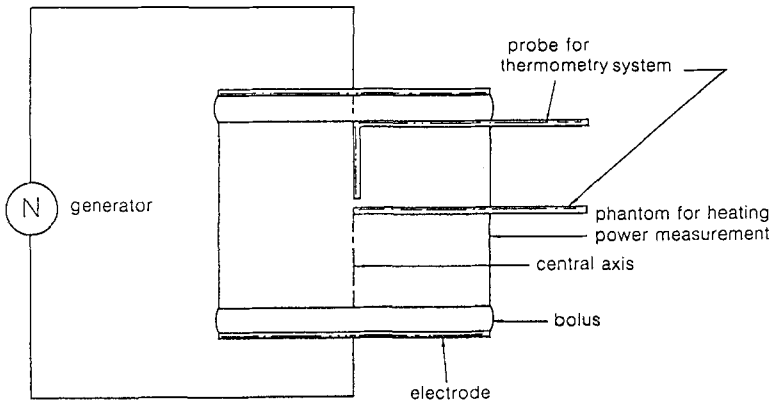

Figure 6. Arrangement for probe insertion for checking stability against electromagnetic fields and AC line noise.

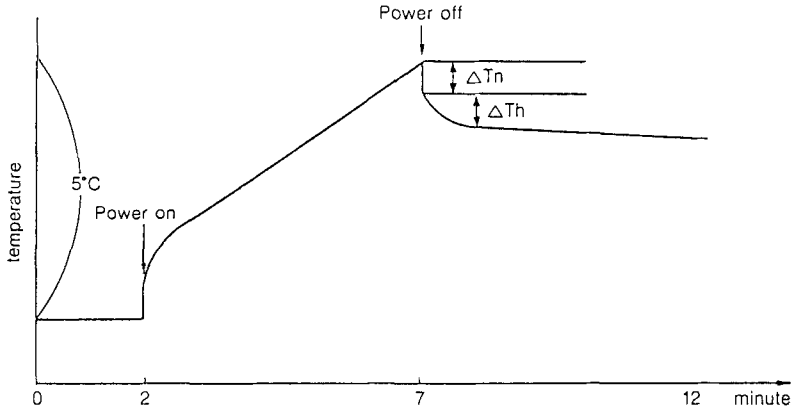

Figure 7. Example of change in thermometer reading with time during a check of its stability against electromagnetic fields and AC line noise. When there is an artifact due to noise, there is an abrupt change in the reading, ΔTn, at the moment the RF power is turned off. When local heating around the probe is induced by RF, the temperature reading decays at the time constant of several seconds when RF power is turned off, and then the temperature reading decays gradually at the time constant of more than several minutes. ΔTh indicates the artifact due to such local heating.

A.3. *Acceptable range of error*

Each error in the accuracy sections describing comparative calibration, temporal stability and stability against electromagnetic field and AC line noise is to be within the range described in §A.1. If any error is not within the range described in §A.1., then the sum of all these errors should be less than 0·6°C.

A.4. *Frequency of checking*

The thermometry system should be checked as follows:

1. upon delivery;
2. at 6-monthly intervals;

3. just before use, should the system have been left unused for a long time;
4. whenever readings are questionable.

When cases (2)–(4) are difficult to achieve for all three categories described in §A.1., the minimum requirements is that the check for 'accuracy in comparative calibration' should be performed. The minimum requirement is that calibration should be performed at a single point using a water bath or fixed point such as gallium.

Appendix B: Remarks

Comment A

SWR is the abbreviation for standing wave ratio and refers to the magnitude of the standing wave which is produced when some reflection of the incident wave occurs. The value increases when the amplitude of the reflected wave increases. SWR is indicated on the SWR meter of the heating system and its value should be adjusted to be as close to unity as possible.

In the case of heating systems which indicate forward and reflected power rather than SWR, the matching should be adjusted so as to reduce the reflected power to less than 20% of the forward power (corresponding to SWR $\leq 1 \cdot 5$).

Comment B

The two feeder cables should be arranged so that they are apart from each other and away from the operators, the patient and other objects.

Comment C

The phantom is designed to match the conductivity of muscle at 13·56 MHz at 37°C. (The conductivity and permittivity of muscle are 0·62 S m^{-1} and 149, respectively.)

Comment D Specification of the working standard thermometer recommended by QA committee for calibration

Type: double-tube mercury-in-glass working standard thermometer with immersion line.
Length and outer diameter: 400 mm × 10 mm OD.
Immersion depth: 100 mm above the bottom of the bulb.
Scale markings: 0°C; 30–50°C.
Minimum scale interval: 0·05°C.
Calibration points (°C): 0, 30, 35, 40, 45, 50.
Traceable accuracy: ±0·03°C.
0°C compensation can be performed.
Exposure compensation can be performed.
Materials: T. K. G.-Pylas glass.

Comment E Specification of water bath

The water bath must have a stirring device and should have a temperature variation of less than 0·1°C within the region ±5 cm from the centre of the tank. Japanese Industrial Standard B7413 refers to the configuration of precision water baths.

Acknowledgement

This English version of the QA guideline was translated by cooperation with Dr J. W. Hand of MRC Cyclotron Unit, Hammersmith Hospital, London, UK. The QA Committee of the Japanese Society of Hyperthermic Oncology expresses their cordial thanks to him.